



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/533,559	03/22/2000	Randy M. Berka	5849.200-US	6980

25907 7590 11/07/2002

NOVOZYMES BIOTECH, INC.  
1445 DREW AVE  
DAVIS, CA 95616

EXAMINER
----------

BRUSCA, JOHN S

ART UNIT	PAPER NUMBER
----------	--------------

1631

DATE MAILED: 11/07/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/533,559

**Applicant(s)**

BERKA ET AL.

**Examiner**

John S. Brusca

**Art Unit**

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 03 September 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 90-102 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 90-102 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \*   c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

Art Unit: 1631

### DETAILED ACTION

The papers received on 03 September 2002 (certificate of mailing dated 23 August 2002) have not been made part of the permanent records of the United States Patent and Trademark Office (Office) for this application (37 CFR 1.52(a)) because of damage from the United States Postal Service irradiation process. The above-identified papers, however, were not so damaged as to preclude the USPTO from making a legible copy of such papers. Therefore, the Office has made a copy of these papers, substituted them for the originals in the file, and stamped that copy:

COPY OF PAPERS

ORIGINALLY FILED

---

If applicant wants to review the accuracy of the Office's copy of such papers, applicant may either inspect the application (37 CFR 1.14(d)) or may request a copy of the Office's records of such papers (*i.e.*, a copy of the copy made by the Office) from the Office of Public Records for the fee specified in 37 CFR 1.19(b)(4). Please do **not** call the Technology Center's Customer Service Center to inquiry about the completeness or accuracy of Office's copy of the above-identified papers, as the Technology Center's Customer Service Center will **not** be able to provide this service.

If applicant does not consider the Office's copy of such papers to be accurate, applicant must

Art Unit: 1631

provide a copy of the above-identified papers (except for any U.S. or foreign patent documents submitted with the above-identified papers) with a statement that such copy is a complete and accurate copy of the originally submitted documents. If applicant provides such a copy of the above-identified papers and statement within **THREE MONTHS** of the mail date of this Office action, the Office will add the original mailroom date and use the copy provided by applicant as the permanent Office record of the above-identified papers in place of the copy made by the Office. Otherwise, the Office's copy will be used as the permanent Office record of the above-identified papers (*i.e.*, the Office will use the copy of the above-identified papers made by the Office for examination and all other purposes). This three-month period is not extendable.

#### ***Election/Restrictions***

In the Office action mailed 25 February 2002 the species requirement incorrectly included the species listed in claim 34. Claim 34 lists alternative sources of sample nucleic acids. The species requirement was for EST probe nucleic acids. The election of the applicants of SEQ ID NOS:4377-7401 as the species of probes satisfies the species requirement.

Applicant's election of Group 1 and combination of probes SEQ ID NOS:4377-7401 in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The applicants have cancelled claims 3-5, 12, 13, 26-28, 41, 42, 62, 64, and 65 drawn to nonelected species or inventions.

#### ***Claim Rejections - 35 USC 101 and 112***

Art Unit: 1631

Newly filed claims 90-102 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility for reasons of record in the Office action mailed 25 February 2002.

Newly filed claims 90-102 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by a substantial utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention for reasons of record in the Office action mailed 25 February 2002.

Applicant's arguments filed 03 September 2002 have been fully considered but they are not persuasive. The applicants have failed to provide evidence that any of the probes in the elected combination of probes could be used for a substantial utility. The applicants suggest the claimed method could be used to measure levels of expression of the genes that correlate with the elected probe combination, however there is no evidence that such measurements could be used for any purpose other than to perform additional research on the genes that correlate with the elected combination of probes. Such a method does not have a substantial utility.

Newly filed claims 90-102 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description

Art Unit: 1631

rejection. The rejection is maintained for reasons of record in the Office action mailed 24 February 2002.

Applicant's arguments filed 03 September 2002 have been fully considered but they are not persuasive. The applicants state that one of skill in the art would be enabled to make the elected combination of probes, however the rejection is for lack of written description of the full breadth of the claimed invention rather than for lack of enablement. The applicants state that avoiding infringement of claims limited to the sequences consisting of the elected combination of probes would be simply a matter of using conservative substitution mutants is not understood because the claimed method is not drawn to expression of polypeptides, rather it is drawn to a method of using an array of probes. While it may be true that avoiding infringement of claims drawn to a method of using probes consisting of the elected combination of probes could be successfully performed by one of skill in the art while still producing results equivalent to the claimed methods, such considerations are not relevant to questions of patentability under 35 U.S.C. § 112, first paragraph. The rejection is maintained for all pending claims because all pending claims are broad enough to apply to use of undescribed cDNA sequences and/or genomic sequences as probes.

The rejection of claims 1, 2, 11, 19, 20, 34, and 40 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention in the Office action mailed 24 February 2002 is withdrawn in view of the amendment filed 03 September 2002.

Art Unit: 1631

***Claim Rejections - 35 USC § 103***

The rejection of claim 20 under 35 U.S.C. 103(a) as being unpatentable over DeRisi et al. in view of Machida et al. in view of Minetoki et al. in view of Hata et al. is withdrawn in view of the amendment and arguments presented by the applicants in the amendment filed 03 September 2002.

The Office action mailed 24 February 2002 contained an error in the rejection under 35 U.S.C. § 103(a). The rejected claim was listed as claim 20 rather than the intended claims 1, 2, 11, 19, 34, and 40. The references cited in the rejection did not show the elected combination of SEQ ID NOS as claimed in originally filed claim 20. Claims 1, 2, 11, 19, 34, and 40 did not recite that limitation and were viewed as properly rejectable over DeRisi et al. in view of Machida et al. in view of Minetoki et al. in view of Hata et al. The rejection of claim 20 was improper because the cited references did not show the elected combination of SEQ ID NOS, as discussed by the applicants in their response filed 03 September 2002. All currently pending claims (newly filed claims 90-102) are limited to methods of using the elected combination of SEQ ID NOS and are not anticipated or obvious over the prior art.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

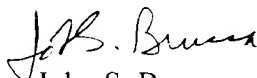
Art Unit: 1631

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 703 308-4231. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703 308-4025. The fax phone numbers for the organization where this application or proceeding is assigned are 703 746-5137 for regular communications and 703 746-5137 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

  
John S. Brusca  
Primary Examiner  
Art Unit 1631

jsb  
November 5, 2002